Design Review

Date:

Product/Project Name:

Team:

Design Phase:

Approve or reject the following design phase of …

As Applicable (Identify input, associated output, and known verification/validation results):

INPUT (e.g., requirement/specification)	OUTPUT (e.g., procedure, drawing, test method, validation protocol, etc.)	REVIEW/RESULTS (e.g., pass/fail, accept/reject, etc.)
Market availability and clinical need for a sterile supplied, reusable ophthalmic knife product line.	Initiate design process for the manufacture and sale of a sterile supplied, reusable ophthalmic knife product line.	Accept

NOTES/COMMENTS:

Design Phase Approved (circle): [Yes] | [No] (Cancelled / Hold / Phase needs additional information)

Design Review Meeting Attendees:

Print Name: _____	Date: _____
Signature: _____	Title: _____
Print Name: _____	Date: _____
Signature: _____	Title: _____
Print Name: _____	Date: _____
Signature: _____	Title: _____
Print Name: _____	Date: _____
Signature: _____	Title: _____
Print Name: _____	Date: _____
Signature: _____	Title: _____
Objective Participant: _____	

Design Performance Specification for (Product Name, Team)

A. PERFORMANCE CHARACTERISTICS	
1. Indications for Use of Product (e.g., general description of product, purpose)	
2. Clinical Procedure for Use	
3. Relevant Setting/Use Environment	
4. Medical Specialty of User	
5. Patient Population Inclusion/Exclusion Criteria	
6. User Interface/Ergonomic Considerations	

B. PRODUCT CHARACTERISTICS	
1. Functional Characteristics (dimensional – limits and tolerances, etc.)	
2. Chemical Characteristics (describe the direct chemical interactions of the product in preparation for and during a procedure)	
3. Biological Characteristics (e.g. duration of product use in-vivo, body fluids and tissue to which the item might be exposed, toxicity and biocompatibility requirements)	
4. Environmental Characteristics (describe anticipated conditions in transportation, storage, and use)	
5. Packaging	
6. Equipment Interface (e.g., power source, connections, accessories, etc necessary for use of the product.)	
7. Safety and Reliability Requirements	

C. MARKETING REQUIREMENTS	
1. Intended Marketplace	
2. Labeling	

3. Claims (e.g., competitors features and claims to which the device is to be compared)	
4. Registration and Patents, Trademarks, and Licensing Agreements (if any)	
5. MDR's/Complaints History	

D. REGULATORY/ QUALITY ASSURANCE	
Technical File Listing Number	
EU ISO Classification	☐ I ☐ Is ☐ Im ☐ II ☐ Other_____
Health Canada Classification	☐ I ☐ II ☐ Other_____
FDA Classification	☐ I ☐ II ☐ Other_____
FDA Product Code	
FDA Regulation Number	
Market Approval Requirements (check if applicable)	☐ FDA Exempt ☐ Device Listing ☐ PMA ☐ 510K
Relevant Regulatory or Statutory Requirements	

E. MANUFACTURING DOCUMENTATION/ MISC. REQUIREMENTS	
Manufacturing Documentation (check if applicable)	☐ DMR ☐ DHR ☐ Drawings ☐ Other:_____
Supplier Requirements	Supplier must satisfy requirements of OP 06-02, "Purchasing Procedure"
Other Requirements	

APPROVALS
Sign/Date_____ Title
Sign/Date_____ Title
Sign/Date_____ Title
Sign/Date_____ Title

Sign/Date_____ Title_____
(Objective Participant) Sign/Date_____

Final Design Review & Launch Presentation

Product Name	
Team	
Date	

Product Review and Launch Questions	
Have all prior gate documents been reviewed and their requirements fulfilled?	☐ Yes ☐ No ☐ N/R
(Discovery, Input, Output, Verification & Validation Gates)	
Has regulatory clearance been conducted?	☐ Yes ☐ No ☐ N/R
Has product listing in Tech. File been updated?	☐ Yes ☐ No ☐ N/R
Have the product drawing(s) been released?	☐ Yes ☐ No ☐ N/R
Has the product DMR/DHR been released?	☐ Yes ☐ No ☐ N/R
Have the product label(s) been released?	☐ Yes ☐ No ☐ N/R
Design review committee approves final design & sale of products?	☐ Yes ☐ No
(Marketing material may be released to external publications)	

Comments/ Explain N/R from checklist above

Final Design Review Meeting Attendees		
Signature	Date	Title

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